Comparison of the Supraflex Cruz 60 micron stent strut versus the Ultimaster Tansei 80 micron stent strut in High Bleeding Risk PCI population

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The objective is to compare the outcome of the ultrathin stent strut Supraflex Cruz stent to the thin stent strut Ultimaster Tansei stent in a PCI population at high risk for bleeding (HBR).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON49235

Source
ToetsingOnline

Brief title
Compare 60/80 HBR

Condition

- Coronary artery disorders

Synonym
bleeding, PCI

Research involving
Human

Sponsors and support

Primary sponsor: Research Maatschap Cardiologen Rotterdam Zuid
Source(s) of monetary or material Support: Grant van Sahajanand Medical Technologies

(SMT),Sahajanand Medical Technologies Pvt. Ltd

Intervention

Keyword: High bleedings risk, PCI

Outcome measures

Primary outcome

The primary endpoint Net Adverse Clinical Endpoints (NACE) defined as a composite of cardiovascular death, myocardial infarction, target vessel revascularization, stroke and bleeding events defined as BARC 3 or 5 at 12 months follow-up after the index PCI.

Secondary outcome

The secondary endpoints of the study are the following:

1) Major adverse cardiac and cerebral events (MACCE) defined as a composite of cardiac death, myocardial infarction, target vessel revascularization and stroke

2) Major or clinically relevant non-major bleeding (MCB) defined as a composite of type 2, 3 and 5 BARC bleeding events

3) Target Lesion Failure (TLF) is defined as cardiac death, myocardial infarction attributed to the target vessel and clinically indicated target lesion revascularization

4) Target Vessel Failure (TVF) is defined as cardiac death, myocardial infarction attributed to the target vessel and clinically indicated target vessel revascularization

5) The individual components of the composite primary endpoint

6) The composite of cardiovascular death, myocardial infarction and stroke

7) The composite of cardiovascular death, myocardial infarction, stroke and

major bleed according to BARC 3 and 5

8) Stent thrombosis according to the ARC definitions

9) Myocardial infarction

10) Urgent target vessel revascularization

11) Non-target vessel revascularization (urgent and non-urgent)

12) Clinically indicated target vessel revascularization

13) Bleeding events according to the BARC, TIMI and GUSTO classification

14) Transfusion rates both in patients with and/or without clinically detected

over bleeding

15) Event rates according to the PRECISE-DAPT score

16) Procedural and device success

Study description

Background summary

Ultrathin strut stents have shown in vivo to be less thrombogenic compared to thicker strut stents due to lower endothelial shear stress and flow disturbances, which limit platelet activation. Furthermore, reduction in strut thickness has also been shown to mitigate inflammation, vessel injury and neointimal proliferation .These advantages seem to have effect in clinical endpoints. Delayed strut coverage, associated with thick stent struts, is an established predictor of late stent thrombosis. A recent meta-analysis showed that ultrathin strut DES are associated with a relative risk reduction in TLF at 1 year compared to thicker strut.

Supraflex Cruz is a new ultrathin (60 micron thick stent strut) DES and the successor of the Supraflex stent, which showed non inferiority compared to the thin strut Xience stent in the **all-comers** TALENT trial.

By changing the stent configuration, biodegradable polymer and drug release profile, the Supraflex Cruz is a new ultrathin strut DES and is considered now one of the most deliverable stent on the market.

In patients with high bleeding risk (HBR) a shorter dual anti-platelet therapy (DAPT) duration is recommended by the European and American guidelines. Although a shorter DAPT duration mitigates the bleeding risk, it can enhance the risk on stent thrombosis and ischemic events on the other hand. Ultrathin stent struts might reduce these ischemic events in the presence of shorter DAPT duration. Therefore, dedicated stent studies are needed to assess the value of ultrathin stent struts in high-risk PCI populations, like HBR patients.

No data exists of the Supraflex Cruz in a subset of patients with HBR during and after PCI. In that respect, a direct comparison to the thin strut (80 micron) biodegradable polymer abluminal sirolimus-eluting Ultimaster Tansei stent, which is known for rapid endothialization and which is large-scale investigated in a landmark trial with HBR patients (Master-DAPT trial) is useful to establish the safety and efficacy of Supraflex Cruz in this important patient population.

Study objective

The objective is to compare the outcome of the ultrathin stent strut Supraflex Cruz stent to the thin stent strut Ultimaster Tansei stent in a PCI population at high risk for bleeding (HBR).

Study design

An Investigator-initiated, multi-center, randomized clinical trial in HBR patients receiving PCI with Supraflex Cruz or Ultimaster Tansei stents

Intervention

Patients are treated according to the randomized regimen at index PCI and at planned staged procedures. Either with the ultrathin stent strut Supraflex Cruz stent to the thin stent strut Ultimaster Tansei stent

Study burden and risks

Patient selection takes place before scheduled PCI with written informed consent. In acute patients selection is allowed after diagnostic coronary angiography on the table with witnessed oral consent in case patients will undergo immediate PCI.

After successful wiring of the first target lesion during the index PCI patients are randomized to receive Supraflex Cruz stents or Ultimaster Tansei stents.

DAPT treatment (combination and duration) is according to the Guidelines of the European Society of Cardiology for Myocardial Revascularization.

Follow-up is scheduled at 1 month, 6 months and 12 months post index PCI procedure. All follow-up visits are preferably scheduled as a visit to outpatient clinic. If patients are unable or unwilling to visit the outpatient clinic, the scheduled visit can be replaced by a telephone call except for the follow-up occurring at 12 months.

Patients are informed that data are collected at the index PCI and at scheduled follow-ups as well as at unscheduled visits.

The investigator monitors the occurrence of Serious Adverse Events (SAEs) for each subject during the course of the study. For the purpose of this protocol, the reporting of SAEs begins directly after randomization when the first study stent leaves the guiding catheter.

CK, CK-MB and Troponine I or T are measured before or at the start of the PCI and after PCI.
No blood-samples are taken at follow-up visits.
The burden for the patient are the scheduled follow-up visits at 1-6-12 months post index PCI.

The risks for the patient do not differ from any other PCI.

No direct benefit of the patient is expected, but important data will be collected for future treatment of the HBR population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients are eligible for inclusion into the study if the following criteria are met:
• Patients of 18 years and above
• Written or witnessed oral consent to participate in the study
• Native coronary artery lesions eligible for PCI with stents with no restrictions in number of lesions and stents, vessel size or lesion complexity, apart from stent thrombosis.
• Patients at high risk for bleeding according to the HBR ARC criteria.
Patients meet the HBR ARC criteria if >=1 major or >=2 minor criteria are met.
Major HBR criteria are the following:
-Clinical indication for treatment with oral anticoagulants (OAC/NOAC) for at least 12 months
- Severe or end-stage chronic kidney failure (GFR <= 30 ml/min)
- Hemoglobin (Hb) level at screening < 11g/dl or < 6.8 mmol/l
- Spontaneous bleeding requiring hospitalization or transfusion in the past 6 months or at any time, if recurrent
- Moderate or severe baseline true thrombocytopenia (platelet count <100 *10-9/L)
- History of chronic bleeding diathesis, like: leukemia, haemophilia, vitamin K deficiency, Factor V or VII deficiency etc.
- Liver cirrhosis with portal hypertension
- Active malignancy (other than skin) within the past 12 months
- Spontaneous intracranial haemorrhage ICH (at any time)
- Traumatic intracranial haemorrhage ICH within 12 months
- Presence of a brain arterio-venous malformation (AVM)
- Moderate or severe ischemic stroke within the past 6 months
- Nondeferrable major surgery on DAPT after PCI
- Recent major surgery or major trauma within 30 days before PCI
Minor HBR criteria are the following:
- Age >= 75 years
- Moderate chronic kidney disease (GFR >30 and <60 ml/min)
- Hemoglobin (Hb) 11-12.9 g/dL / 6.8-8.0 mmol/l for men and 11-11.9 g/dL /

6.8-7.4 mmol/l for women
- Any ischemic stroke at any time not meeting the major criterion
- Spontaneous bleeding requiring hospitalization or transfusion within the past 12 months
- Need for chronic treatment with steroids or non-steroidal anti-inflammatory drugs

Exclusion criteria

Patients are not eligible if any of the following applies:
• Treated with stents other than Supraflex Cruz or Ultimaster within 6 months prior to index procedure
• Treatment of lesions with stent thrombosis
• Treatment of venous or arterial coronary grafts
• Treated for stent thrombosis in 12 months prior to index PCI procedure
• Treated with a bioresorbable scaffold 3 years before index PCI procedure
• Cardiogenic shock at index procedure
• Active SARS-CoV-2 infection of suspicion of SARS-CoV-2 infection
• Cannot provide written informed consent
• Under judicial protection, tutorship or curatorship
• Unable to understand and follow study-related instructions or unable to comply with study protocol
• Active bleeding requiring medical attention (BARC>=2) at index PCI
• Life expectancy less than one year
• Known hypersensitivity or allergy for aspirin, clopidogrel, ticagrelor, prasugrel, cobalt chromium or sirolimus
• Any anticipated PCI after index PCI, unless planned and scheduled at index PCI
• Participation in another stent or drug trial

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2020
Enrollment:	736
Type:	Actual

Medical products/devices used

Generic name:	Drug eluting coronary stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-08-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-09-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL73419.100.20